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EXAMINER	
PATTON, AMANDA K	
ART UNIT	**PAPER NUMBER**
3762	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,331	DALY ET AL.	
	Examiner	Art Unit	
	Amanda Patton	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *13 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-73* is/are pending in the application.

4a) Of the above claim(s) *70-73* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- Group 1, claims 39-69, drawn to a cochlear implant system.
- Group 2, claims 70-73, drawn to a method for repositioning a cochlear implant system.

The inventions listed as Groups 1 and 2 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature of Group 2 is the repositioning of the housing after implantation, whereas Group 1 does not require this special technical feature, as the housing could be rotated as the recipient's head grows.

During a telephone conversation with Michael Verga on January 14, 2008 a provisional election was made without traverse to prosecute the invention of Group 1, claims 39-69. Affirmation of this election must be made by applicant in replying to this Office action. Claims 70-73 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

In response to the amendments to the title and the specification the objections to the specification have been withdrawn. In response to the cancellation of claims 32-34 the rejection under 35 U.S.C. 112, Second Paragraph has been withdrawn. Currently claims 39-69 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 41 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 41, line 2 recites the limitation "wherein first region". Examiner suggests replacing "wherein first region" with "wherein said first region".
- Claim 51, line 3 recites the limitation "and wherein said electronics comprise". It is unclear whether the electronics being referred to are located in the external component having a microphone or in the implantable housing. For the purpose of examination, the electronics are assumed to be the implanted electronics.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 39, 41, 43-49, 55, 57, 59, 62, and 64 are rejected under 35 U.S.C. 102(e) as being anticipated by Berrang et al. (US Pat. 6,648,914, as previously cited).

Regarding **claims 39, 47, 55, and 64**, Berrang discloses the claimed invention including: a housing configured to be implanted in a recipient (e.g. housing sections 2 and 3) comprising electronics configured to output one or more stimulation signals (e.g. Col. 4, lines 25-38); and a first electrode assembly (e.g. electrode array 10) having first and second longitudinally extending continuous regions, wherein the first region is connected to the housing and wherein the second region is configured to be at least partially implanted into a cochlear of the recipient to deliver stimulation to the cochlea in accordance with said one or more stimulation signals wherein the housing and the first region are configured such that following implantation of the second region into the cochlea, the housing is rotatable about an axis that is substantially aligned with a longitudinal axis of the first region such that the second region implanted in the cochlea remains substantially stationary during the rotation; and an external component having a transmitter coil configured to transmit signals from the external component to the receiver coil (e.g. external part 31 comprising coil 53).

Due to the flexible nature of the electrode array and the pliable bridge connecting the two portions of the housing together the housing is capable of rotating about an axis that is substantially aligned with a longitudinal axis of the electrode array when the patient's head

grows, etc. Examiner wishes to note that the claim does not mention how much the housing must be rotatable about the axis, and thus the small rotation possible when the patient's head grows fulfils the limitation of the claims.

Regarding **claims 41 and 57**, Berrang additionally teaches said housing comprising an edge that is most proximate the cochlea, wherein the first region is connected to an edge of the housing most proximate the cochlear (e.g. Figure 3).

Regarding **claims 43-44 and 59-60**, Berrang additionally teaches that the housing is at least partially formed from resiliently flexible material wherein the region adjacent one or more of the edges is resiliently deformable (e.g. pliable bridge 6).

Regarding **claims 45 and 61**, Berrang additionally teaches a housing that is substantially symmetrically about a plane that is parallel to the longitudinal axis of the first region of the electrode array.

Regarding **claims 46 and 62**, Berrang additionally teaches in the alternate embodiments (e.g. Figure 17) a housing configuration that is substantially symmetrical about a plane that is perpendicular to the longitudinal axis of the first region of the electrode array.

Regarding **claim 48-49**, Berrang additionally teaches an external component (e.g. external part 51; Figure 9), and wherein the implantable housing further comprising a receiver coil configured to receive RF signals from the external component (e.g. coil 4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 42 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berrang.

Regarding **claims 42 and 58**, Berrang discloses the claimed invention but does not disclose expressly the placement of the first region of the electrode array that is connected to an edge of the housing that is adjacent to the edge most proximate the cochlea. It would have been an obvious mater of design choice to a person of ordinary skill in the art to modify the housing as taught by Berrang with the placement of the first region of the electrode array that is connected to an edge of the housing that is adjacent to the edge most proximate the cochlea, because Applicant has not disclosed that this placement provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the electrode placement as taught by Berrang, because it provides proper insertion into the cochlea and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Berrang. Therefore, it would have been an obvious matter of design choice to modify Berrang to obtain the invention as specified in the claims.

Claims 40, 50-51, 56, 63, and 65-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berrang in view of Faltys et al. (US Pat 6,272,382, as previously cited, hereafter "Faltys '382").

Regarding **claims 40 and 56**, Berrang additionally teaches a housing that is rotatable about an axis that is substantially aligned with a longitudinal axis of the first region of the

electrode array that extends though the center of the electrode array. Berrang does not expressly teach an electrode array having a substantially circular cross section. Faltys '382 teaches that it is well known in the art to have electrode arrays with substantially circular cross sections (e.g. Figure 2A). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the electrode array with a substantially circular cross section of Faltys '382 in the device of Berrang since such a modification would provide the predictable results of a cochlear array designed for easy implantation into the cochlea.

Regarding **claims 50 and 65**, Berrang does not expressly teach electronics configured to allow transcutaneous bidirectional data transfer between the implantable component and the external component. Faltys '382 teaches that it was known in the art to use a receiver coil that is part of an RF link that allows both traditional transfer of data from the external headpiece coil and the implantable component 14 and back telemetry between the external headpiece coil 52 and the implantable component 14 (Col. 10, lines 20-27, and as shown through bidirectional arrows in Figure 1A-1E). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the bidirectional data transfer of Faltys '382 in the device of Berrang, since such a modification would provide the system with the ability to communicate data between the implanted device and the external component for providing the predictable results of better stimulation based on implant feedback.

Regarding **claims 51 and 66**, Berrang does not expressly teach an external component comprising a microphone. Faltys '382 teaches that it was known in the art to use an external component in cochlear implant system comprising a microphone (e.g. microphone 104 located in headpiece (HP) 106; Col. 7, lines 60-66). It would have been obvious to one having ordinary

skill in the art at the time the invention was made to include the external components of Faltys '382 in the device of Berrang since such a modification would provide the system with a smaller amount of electronics to implant for providing the predictable results of a smaller implant resulting in an easier implantation.

Regarding **claim 63**, Berrang does not expressly teach an external component comprising a microphone configured to receive an input sound and a signal processor configured to convert the inputted sound into a coded signal. Faltys '382 teaches that it was known in the art to use an external component in cochlear implant system comprising a microphone and a signal processor to convert the inputted sound into coded signal (e.g. microphone 107 and speech processor (SP) located in headpiece (HP) 106; Col. 7, lines 60-66). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the external components of Faltys '382 in the device of Berrang since such a modification would provide the system with a smaller amount of electronics to implant for providing the predictable results of a smaller implant resulting in an easier implantation.

Claims 52-54 and 67-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berrang in view of Carter et al. (US Pat. 6,205360, as previously cited, hereafter "Carter").

Regarding **claims 52 and 67**, Berrang does not teach an implantable component comprising a second electrode assembly. Carter teaches a second extra-cochlear electrode assembly 13 (e.g. Figure 1; Col. 6, lines 10-15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a second extra-cochlear

electrode array in the device of Berrang in order to provide the predictable results of a reference electrode not affected by stimulation in the cochlea.

Regarding **claims 53-54 and 68-69**, Berrang and Carter disclose the claimed invention but does not disclose expressly a second electrode assembly connected to an edge of the housing opposing the first electrode assembly and substantially aligned with a longitudinal axis of the electrode array. It would have been an obvious mater of design choice to a person of ordinary skill in the art to modify the second electrode array as taught by Berrang and Carter with the specific placement of the second electrode array, because Applicant has not disclosed that the array placement provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the electrode array arrangement as taught by Berrang and Carter, because it provides proper electrode array placement and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Berrang and Carter. Therefore, it would have been an obvious matter of design choice to modify Berrang and Carter to obtain the invention as specified in the claims.

Response to Arguments

Applicant's arguments with respect to claims 39-69 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Patton whose telephone number is (571) 270-1912. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AKP/
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January 22, 2008

GEORGE R. EVANISKO
PRIMARY EXAMINER
1/22/8